

**Section II. (REMARKS)****Cancellation of Previously Pending Claims 1-30 and Addition of New Claims 31-45**

Previously pending claims 1-30 of the application have been cancelled herein<sup>1</sup>, and new claims 31-45 have been added to claim the invention in a manner consistent with and supported by the Examples set out at pages 22-26 of the instant application.

All such added claims 31-42 are directed to the elected species, mirtazapine, which the examiner has indicated "to be free of the prior art" (page 2, lines 2-3 of the March 2, 2004 Office Action).

In the added claims, no new matter (35 USC 132) has been added.

Claim 31 recites a method of combating movement disorder in a patient experiencing or susceptible to such movement disorder during treatment with a dopaminergic medication, an anticonvulsant medication or an antianxiolytic medication, in which the method comprises administering an effective amount of mirtazapine to the patient. Such claim is consistent with Examples 1-6.

The dopaminergic medication (claim 32) can include a dopa agonist (claim 33; Examples 2 and 3), with specific dopaminergic medication ingredients (claim 34) including levodopa (Example 6), levodopa in combination with carbidopa (Sinemet; Examples 1-3), or ropirinoles (Example 2).

The anticonvulsant medication (claim 35) can include primidone (Mysoline; Example 4) (claim 36).

The antianxiolytic medication (claim 37) can include (Example 5) propranolol (claim 38), an SSRI (claim 39) or a benzodiazepine (claim 40).

The movement disorder (claim 31) can include bradykinesia (claim 41; Examples 1-3), tremor

<sup>1</sup> such claims have been cancelled to advance the prosecution of the present application; this cancellation of claims is with express reservation of the right to claim the subject matter of the cancelled claims in a further divisional or continuing application, as based on and claiming priority of the present application.

(claim 42; Examples 2-6), resting tremor (claim 43; Examples 2, 3 and 6), and action tremor (claim 44, Examples 4 and 5).

A corresponding composition aspect of the invention is claimed in claim 45, including (i) a dopaminergic medication, an anticonvulsant medication or an antianxiolytic medication, and (ii) mirtazapine in an amount effective for combating movement disorder.

**Rejection of Claims on Reference Grounds under 35 CFR §102(b) and 35 USC §103(a)**

In the March 2, 2004 Office Action, the previously pending elected claims 1-14, 16, and 18-30 were rejected on various grounds, including:

a rejection of claims 1-14, 16, 18, 23, 24, 26-28 and 30 "under judicially created doctrine as being drawn to an improper Markush group;"

a rejection of claims 1-14 and 18, 23, 24, 26-28 and 30 under 35 USC 112, first paragraph as non-compliant with the written description requirement;

a rejection of claims 3 and 16 under 35 USC 112, second paragraph as failing to particularly point out and distinctly claim the invention;

a rejection of claims 1-4, 6-12, 13, 26, 27 and 30 under 35 USC 102(b) as anticipated by Henry et al., Experimental Neurology; and

a rejection of claims 1-5, 6-14, 16, 18, 23-28 and 30 under 35 USC 102(b) as anticipated by Lin-Shiau et al., Pharmacol., Biochem. Behav.

These various rejections now are moot in view of the cancellation of the previously pending claims 1-30.

The newly added claims 31-45 have been directed to the elected species, mirtazapine, which as mentioned in the preceding discussion herein has been characterized by the examiner "to be free of the prior art."

Further, the added claims 31-45, as discussed in preceding remarks, are based on and directly supported by the specific examples in the application. Such claims are therefore free of infirmity under 35 USC 112.

Accordingly, all claims 31-45 now pending in the application are patentable over the art and in form and condition for allowance.

**Request for Extension of Time under 37 CFR §1.136**


Request hereby is made for a two month extension of time, extending the time for response to the March 2, 2004 Office Action from June 2, 2004 to August 2, 2004.

The amount of \$210.00 as the fee specified in 37 CFR §1.17(a) is authorized to be charged in the attached credit card authorization form. Authorization is also hereby given to charge any deficiency for this response, in applicable fees or charges, to Deposit Account Number 08-3284 of Intellectual Property/Technology Law.

**Conclusion**

Claims 31-45 are patentably distinguished over the art and are in form and condition for allowance. Favorable action is requested.

Respectfully submitted,

  
\_\_\_\_\_  
Steven J. Hultquist  
Reg. No. 28,021  
Attorney for Applicants

INTELLECTUAL PROPERTY/  
TECHNOLOGY LAW  
Phone: (919) 419-9350  
Fax: (919) 419-9354  
Attorney File No.: 4164-101 CON